


19. Traceability

This guidance note contains:

Mandatory requirements

- Extracts from the HFE Act 1990 (as amended)
- Extracts from licence conditions

 Refer to principles 7, 8 and 10

HFEA guidance

- Traceability requirements



Mandatory requirements

Human Fertilisation and Embryology (HFE) Act 1990 (as amended)

2 Other terms

- (1) “traceability” means the ability—
- (a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
 - (b) identify the donor and recipient of particular gametes or embryos,
 - (c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and
 - (d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

12 General conditions

- (3) It shall be a condition of every licence to which this subsection applies that—
- (a) such information as is necessary to facilitate the traceability of gametes and embryos, and
 - (b) any information relating to the quality or safety of gametes or embryos, shall be recorded and provided to the Authority upon request.

Schedule 3A

Traceability and coding system

- 1 Licence conditions shall require that all persons to whom a licence applies adopt such systems as the Authority considers appropriate to secure—
- (a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive, and
 - (b) in relation to the coding of information, compliance with the requirements of Article 25 (coding of information) of the first Directive and Article 10 (European coding system) of the third Directive.
- 2 Licence conditions imposed in accordance with paragraph 1 may specify the coding system which must be applied in relation to gametes and embryos intended for human application.

Licence conditions

- T99 The centre must establish, implement and comply with documented procedures to ensure that:
- a. all gametes and embryos, and



Mandatory requirements (cont)

- T99 (cont)
- b. all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa.
- T100 The documented procedures referred to in licence condition T98 include the following information:
- a. the unique and accurate identification of each patient/donor
 - b. the unique and accurate identification of each set of gametes and embryos
 - c. date of procurement
 - d. place of procurement
 - e. type of treatment
 - f. description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and
 - g. description of all processing steps applied to the procurement, use and storage of gametes and embryos.
- T101 The centre must ensure that all containers (dishes, vials, ampoules, tubes etc) used in the course of procurement, possessing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (eg, labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.
- T102 The centre must record such information as is necessary to facilitate the traceability of gametes and embryos and any information relating to the quality or safety of gametes and embryos. This information must be provided to the Authority upon request.
- T103 The centre must keep data necessary to ensure traceability for a minimum of thirty years (and for such longer period as may be specified in Directions) in an appropriate readable storage medium.
- T104 Records not covered by licence condition T103 and test results that impact on the safety and quality of the embryos and gametes, must be kept so as to ensure access to the data for at least 10 years after the expiry date, clinical use or disposal.



HFEA guidance

Traceability requirements

- 19.1** Procedures for ensuring traceability of gametes and embryos should be documented. Centres should ensure that:
- (a) they uniquely and accurately identify:
 - (i) the patient
 - (ii) the patient's partner, donor or both, as applicable
 - (iii) gametes and embryos, and
 - (iv) any containers used for the receipt and distribution of gametes and embryos.
 - (b) quarantined, non-quarantined and rejected material is clearly distinguishable at all processing stages.



19.1 (cont)

- (c) they keep records of the equipment and materials used to receive, process, store and discard gametes and embryos
- (d) they keep registers of received, processed, stored, distributed and discarded gametes or embryos. Registers should enable a centre to investigate adequately if a problem is identified after the gametes have been used. Registers should also enable the centre to identify:
 - (i) a patient, patient's partner or donor
 - (ii) processing steps applied to gametes or embryos (or both) and, if applicable, third parties involved in processing
 - (iii) individual procurement of gametes and embryos
 - (iv) the institution from which gametes and embryos have come
 - (v) distributed gametes or embryos, and
 - (vi) the institutions to which gametes or embryos have been sent (whether for a patient's use or for research).

19.2 For the system of identification, centres should use an identifying code that contains at least the following information:

- (a) for donors:
 - (i) their identity, and
 - (ii) the centre's identity.
- (b) for gametes and embryos:
 - (i) a unique code
 - (ii) split number (if applicable), and
 - (iii) end of statutory storage period.

19.3 The centre's traceability procedures should cover any materials or equipment that could affect the quality or safety of gametes and embryos, for example:

- (a) culture media
- (b) serial numbers or batch numbers of equipment and materials coming into contact with gametes and embryos, and
- (c) records of the monitoring and maintenance of the required conditions in incubators and storage tanks.

See also guidance note:

- [26 – Equipment and materials](#)

19.4 For gametes that have been stored at the centre (eg, for oncology or pre-vasectomy patients) and then supplied to another centre (eg, to be stored or used in treatment), the centre will not be expected to hold traceability data for subsequent processes involving those gametes outside the centre. However, the storing centre's record keeping procedures should show a link to the centre to which the gametes are supplied, so that the complete process from procurement to use or disposal can be traced if needed.